

SEP 11 2001

DADE BEHRING

Summary of Safety and Effectiveness Information

K012233

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

**Submitter's Name:** Elaine H. Kindell  
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**Date of Preparation:** July 12, 2001

**Device Name:** Stratus® CS Troponin I Calibrator (cTnI Cal Pak)

**FDA Classification Name:** Calibrator, secondary

**Predicate Device:** Stratus® CS TROP CalPak (K983722)

**Device Description:** The Stratus® CS cTnI CalPak is a plastic cartridge, which contains buffered bovine protein with native human troponin complex in three of the reagent wells. The approximate concentration to troponin complex per well is 40 ng/mL. The CalPak is a single-use product.

**Intended Use:** The Cardiac Troponin I Calibrator (cTnI CalPak) is intended to be used for calibration of the cardiac troponin I method on the Stratus® CS analyzer.

**Comparison to Predicate Device:**

Item	Stratus® CS cTnI Cal Pak (modified)	Stratus® CS TROP Cal Pak (K983722)
Intended Use	Calibrator	Calibrator
Analyte	Native human troponin complex	Native human troponin complex
Matrix	Normal human serum	Buffered bovine protein
Form	Frozen	Frozen
Target Concentration	40 ng/mL	40 ng/mL
Values	Assigned	Assigned
Packaging Configuration Values	Single use plastic cartridge	Single use plastic cartridge
Levels	One	One

**Comments On Substantial Equivalence:** The Stratus® CS cTnI CalPak (modified) is equivalent to the Stratus® CS TROP CalPak (K983722) currently marketed. The modified Stratus® CS cTnI CalPak has uses with a normal human serum base versus the buffered bovine protein matrix and associated stabilizers used in the currently marketed product. Both products are intended to be used as calibrators for the Stratus® CS Cardiac Troponin I method.

**Conclusion:** The modified Stratus® CS cTnI CalPak is substantially equivalent to the Stratus® CS TROP CalPak currently marketed by Dade Behring based on the comparison summarized above.

*Elaine H Kindell*

Elaine H. Kindell  
Quality Assurance and  
Compliance Manager  
Date: July 12, 2001



DEPARTMENT OF HEALTH & HUMAN SERVICES

Ms. Elaine H. Kindell  
Quality Assurance and Compliance Manager  
Dade Behring Inc.  
Glasglow Business Community  
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Newark, DE 19714

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

SEP 11 2001

Re: k012233

Trade/Device Name: Stratus<sup>®</sup> CS Troponin I Calibrator (cTnI CalPak)  
Regulation Number: 21 CFR 862.1150  
Regulation Name: Calibrator  
Regulatory Class: Class II  
Product Code: JIT  
Dated: July 12, 2001  
Received: July 16, 2001

Dear Ms. Kindell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

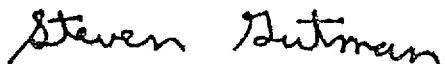
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### **Indications Statement**

Device Name: Stratus® CS Troponin I Calibrator (cTnI CalPak)

Indications for Use: The Cardiac Troponin I Calibrator (cTnI CalPak) is an *in vitro* diagnostic product intended to be used for calibration of the cardiac troponin I method on the Stratus® CS analyzer. This calibrator is a device intended to establish a point of reference that is used in the determination of troponin I values.

*Elaine H. Kindell*  
Elaine H. Kindell  
Quality Assurance and  
Compliance Manager

*July 12, 2001*  
Date

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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#### Concurrence of CDRH, Office of Device Evaluation (ODE)

*Kesia Alexander, Jordan Cooper*  
(Division Sign-off)  
Division of Clinical Devices  
510(k) Number K012233

K012233  
510(k) Number

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#### **Division Sign-Off**

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Office of Device Evaluation

Over-the-counter Use \_\_\_\_\_

(Optional format 1-2-96)